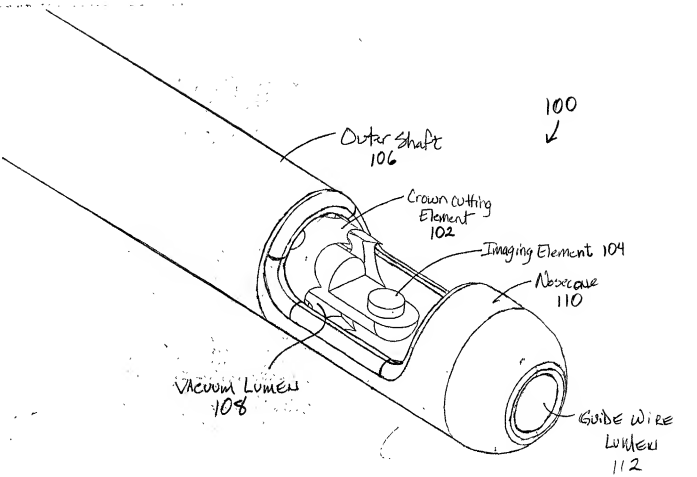

FIGURE 1

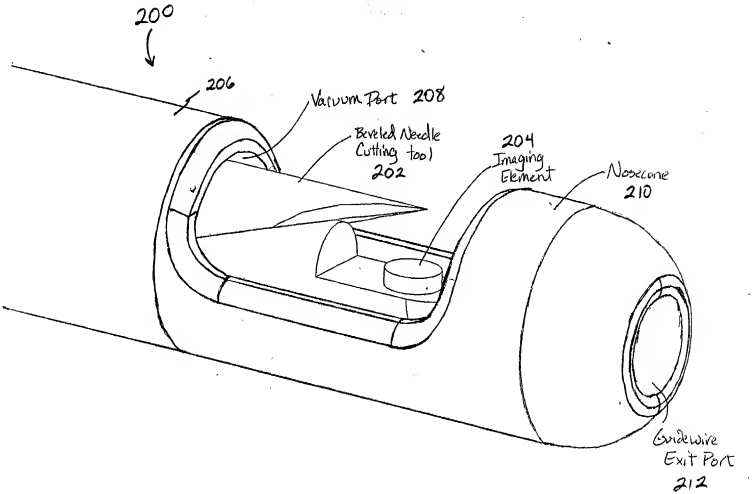
200
206
Vacuum Port 208
Beveled Needle Cutting tool 202
204 Imaging Element
Nosecone 210
Guidewire Exit Port 212

FIGURE 2

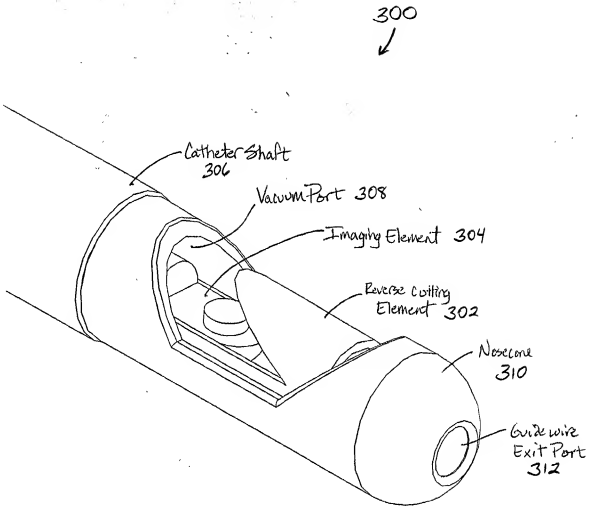

FIGURE 3

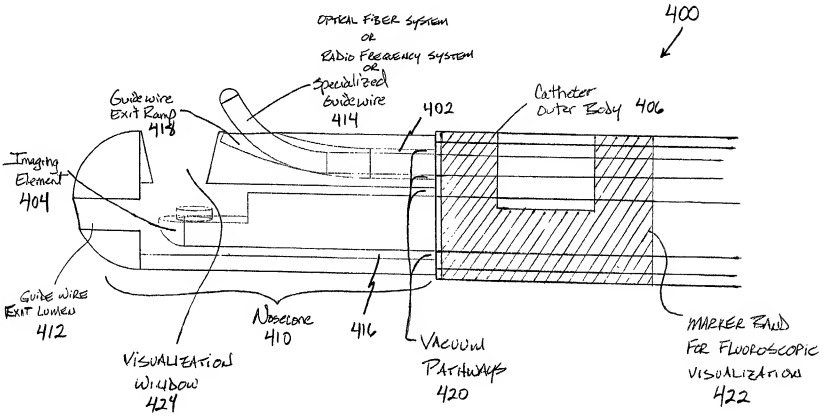

FIGURE 4

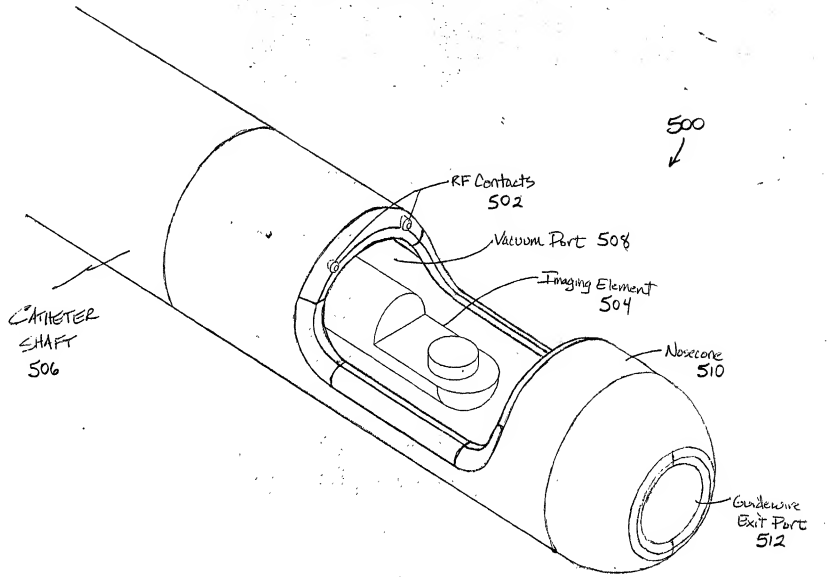
500
RF Contacts
502
Vacuum Port 508
Imaging Element
504
Catheter
Shaft
506
Nosecone
510
Guidewire
Exit Port
512

FIGURE 5

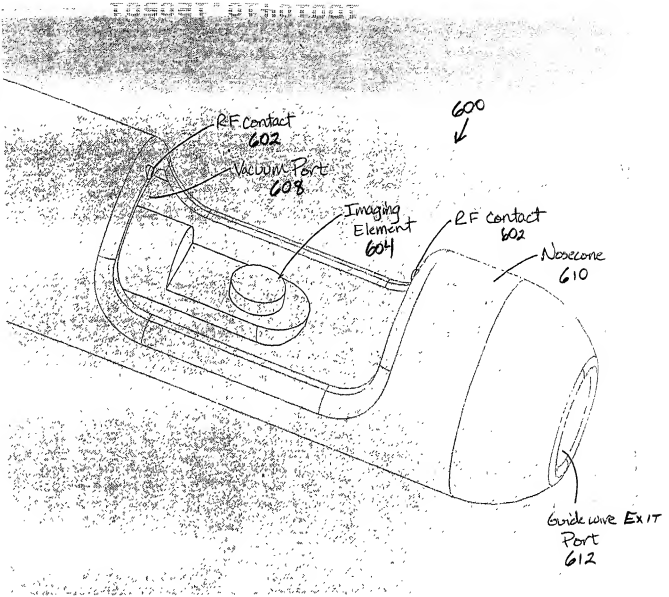
600
RF contact
602
Vacuum Port
608
Imaging
Element
604
RF contact
602
Nosecone
610
Guidewire Exit
Port
612

FIGURE 6

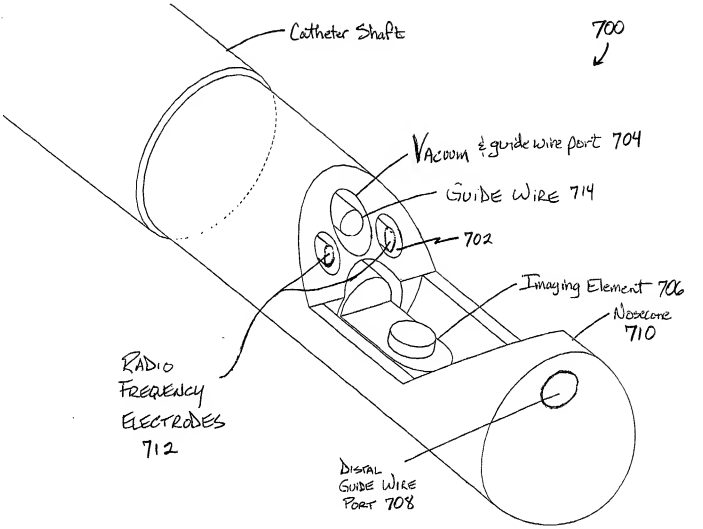

FIGURE 7A

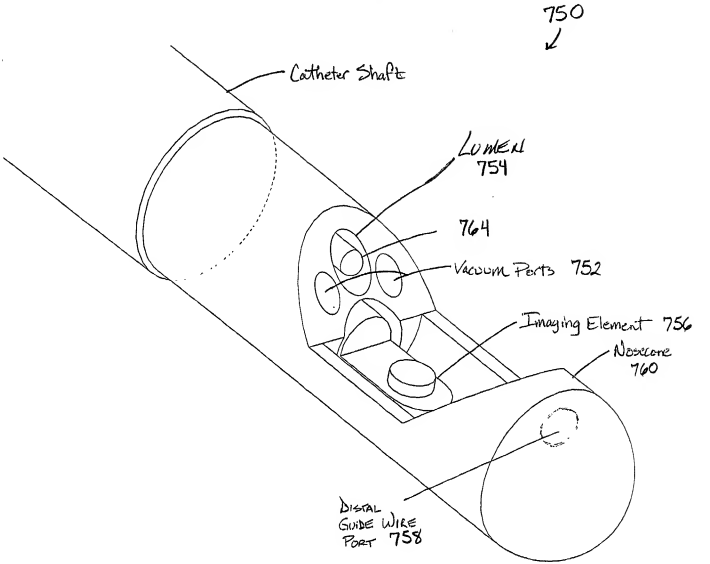
750
Catheter Shaft
Lumen
754
764
Vacuum Ports 752
Imaging Element 756
Nosecone
760
Distal
Guide Wire
Port 758

FIGURE 7B

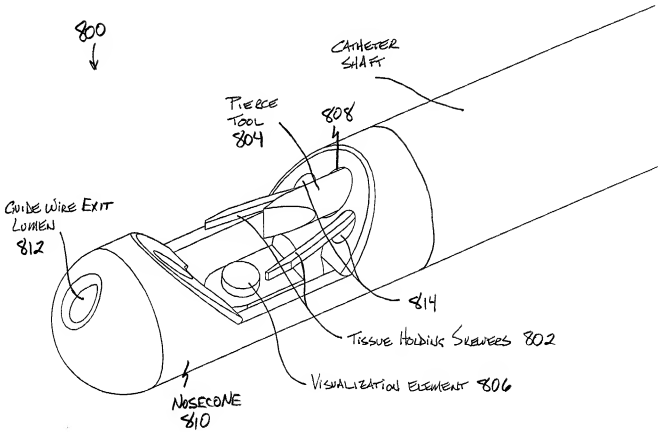

FIGURE 8

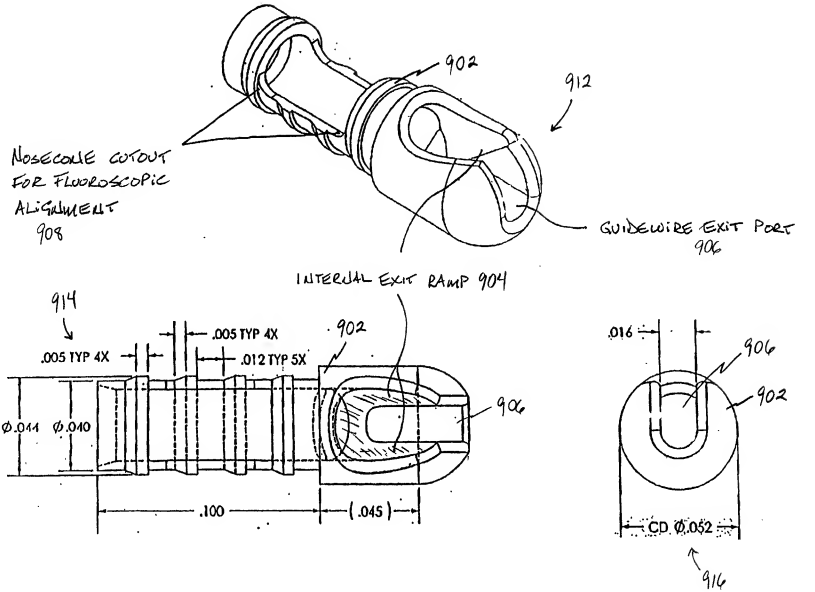

FIGURE 9A

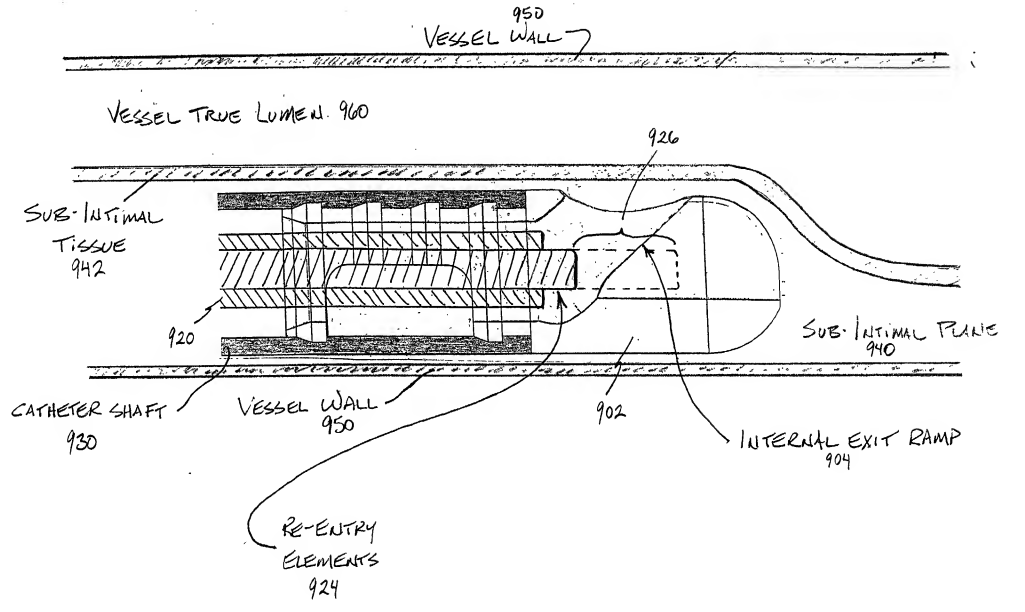

FIGURE 9B

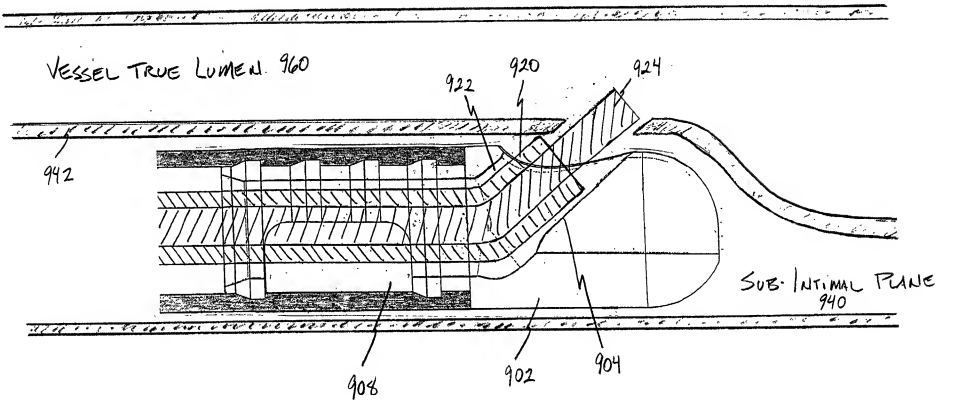

FIGURE 9C

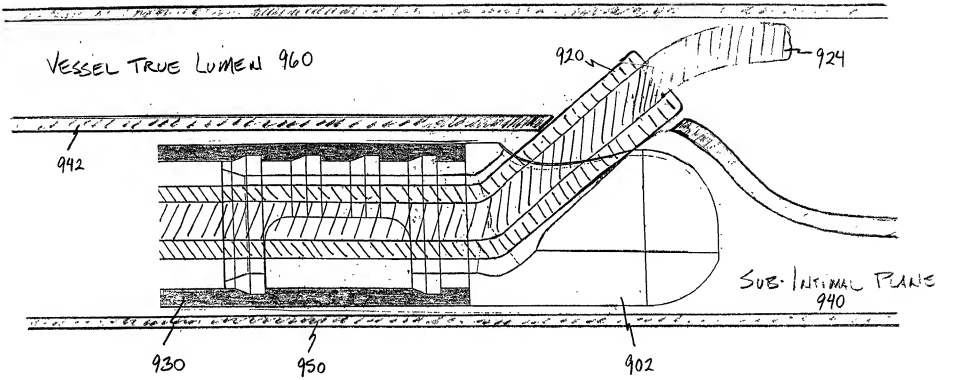

FIGURE 9D

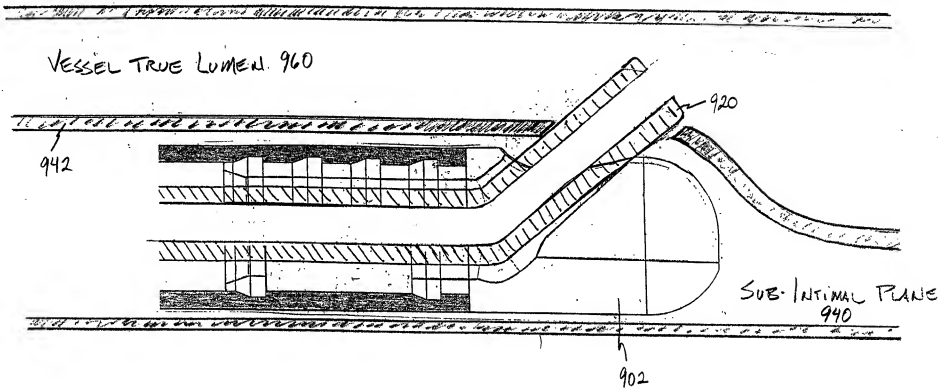

FIGURE 9E

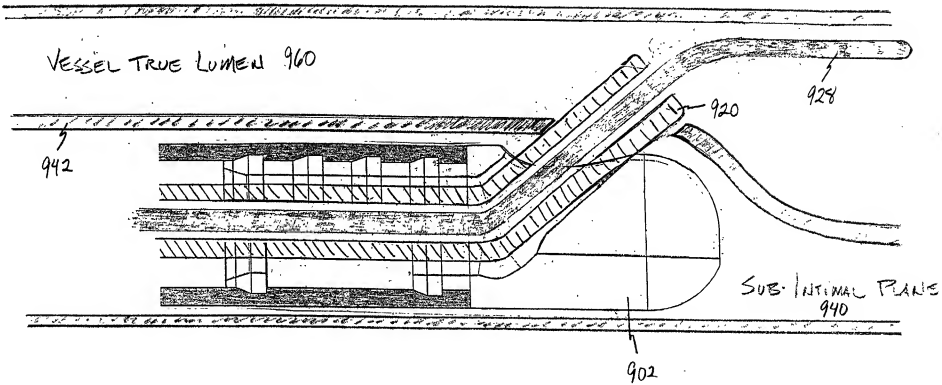

FIGURE 9F

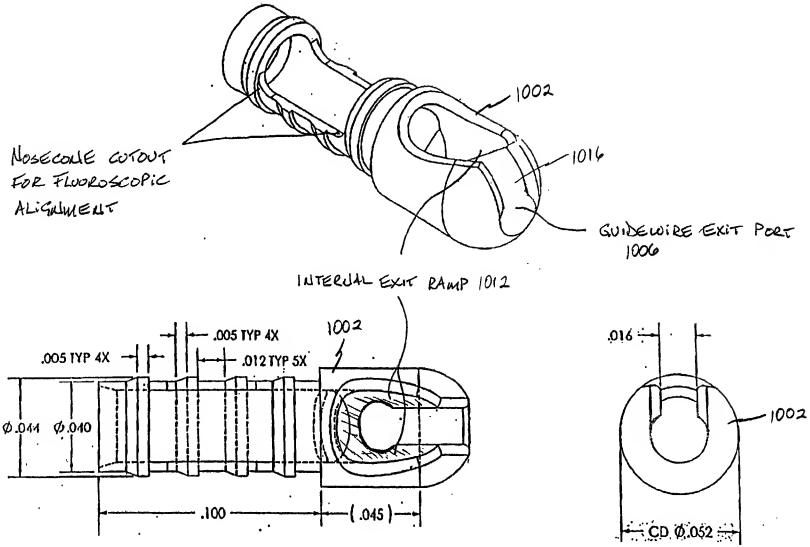

FIGURE 10A

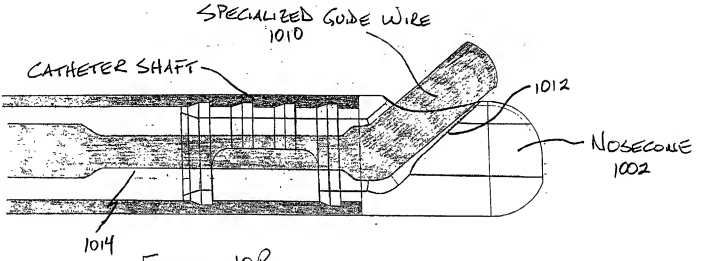

FIGURE 10B

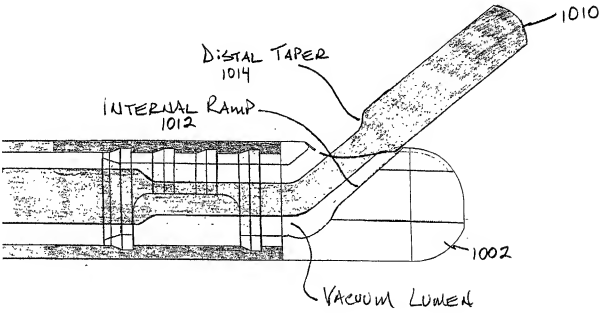

FIGURE 10C

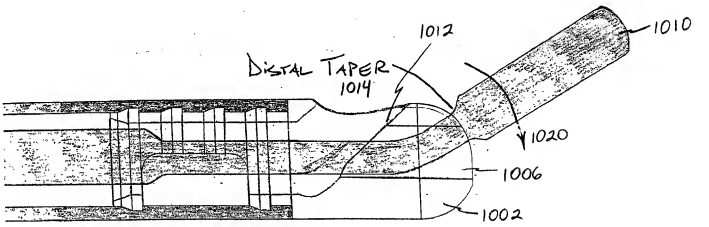

FIGURE 10D

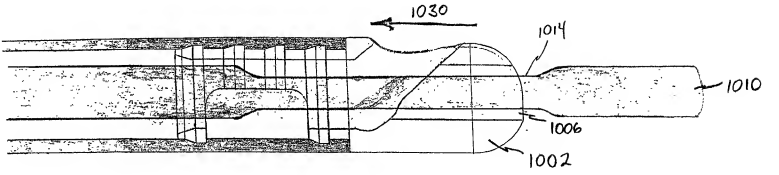

FIGURE 10E

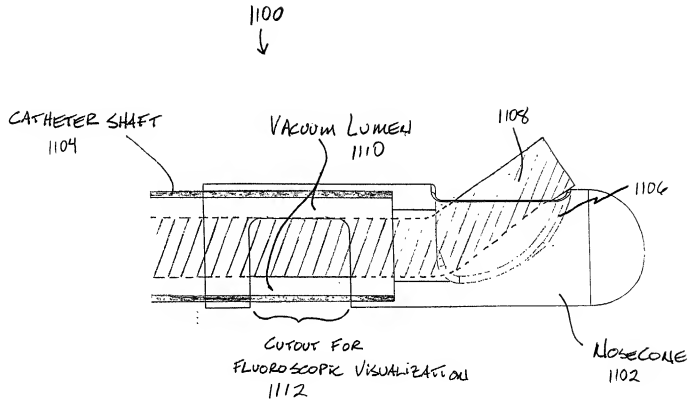

FIGURE 11

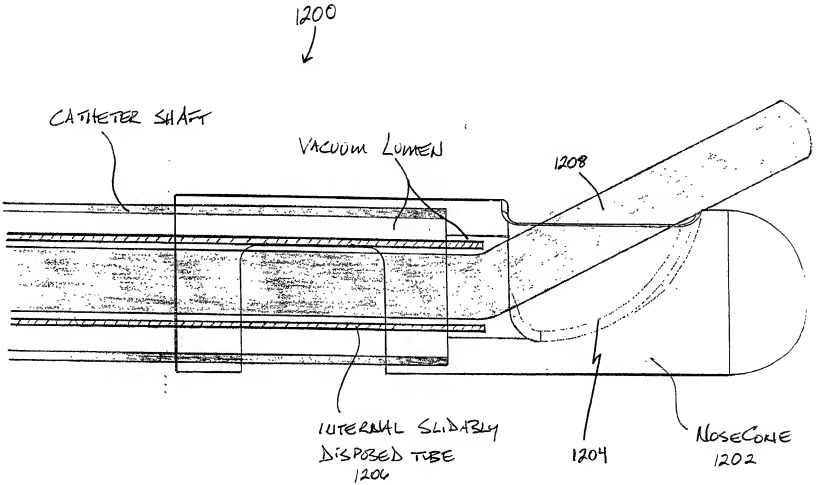

FIGURE 12A

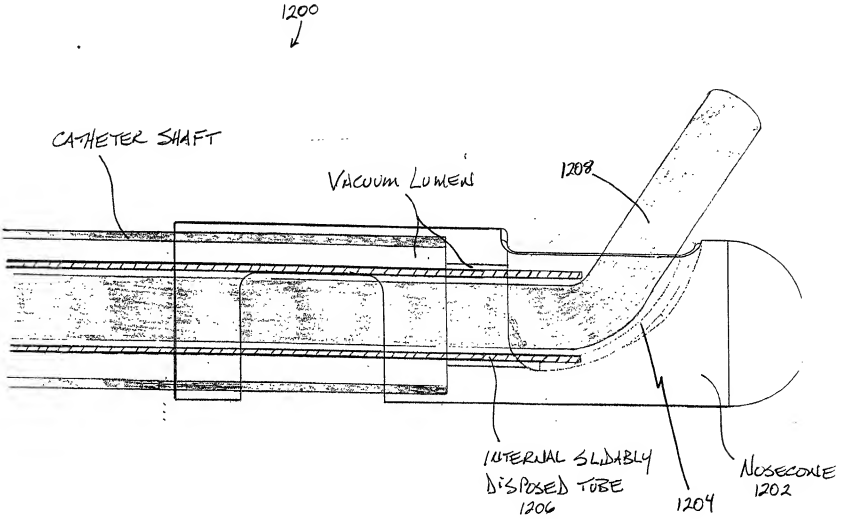

FIGURE 12B

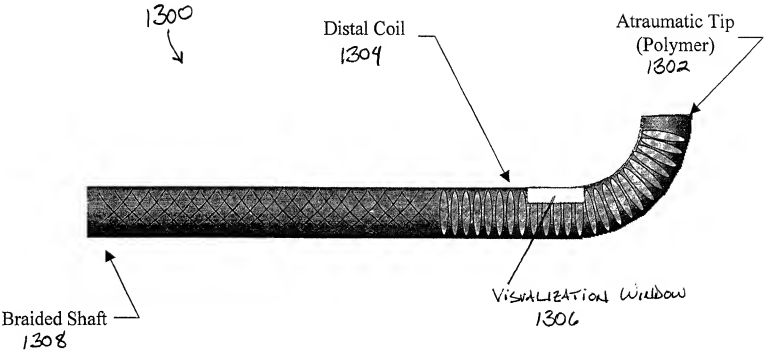

FIGURE 13

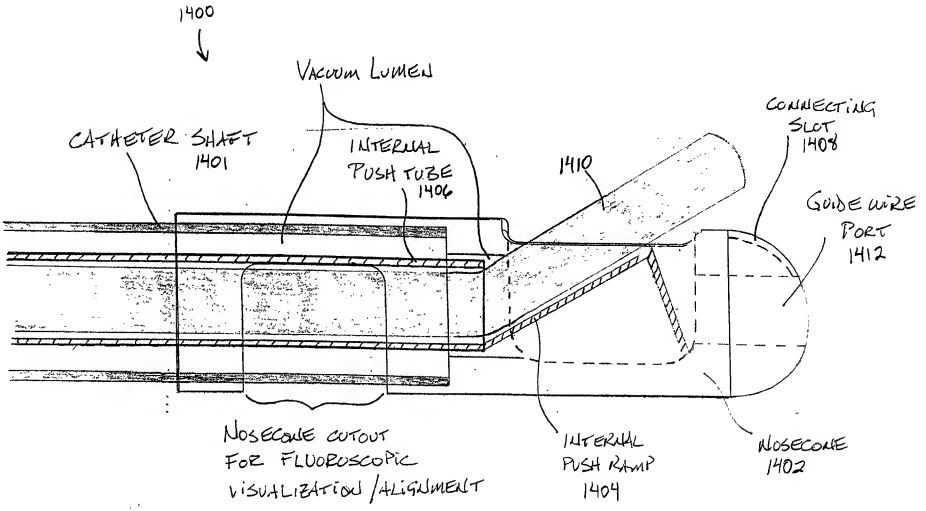

FIGURE 14A

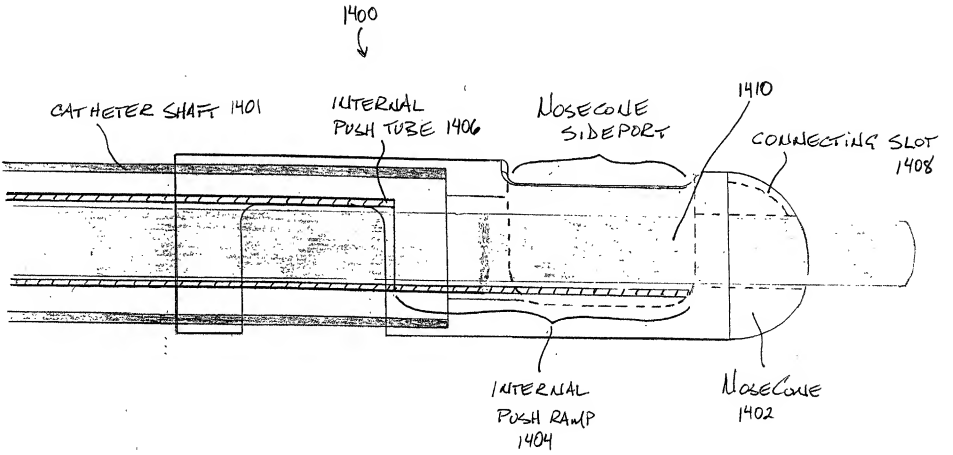

FIGURE 14B

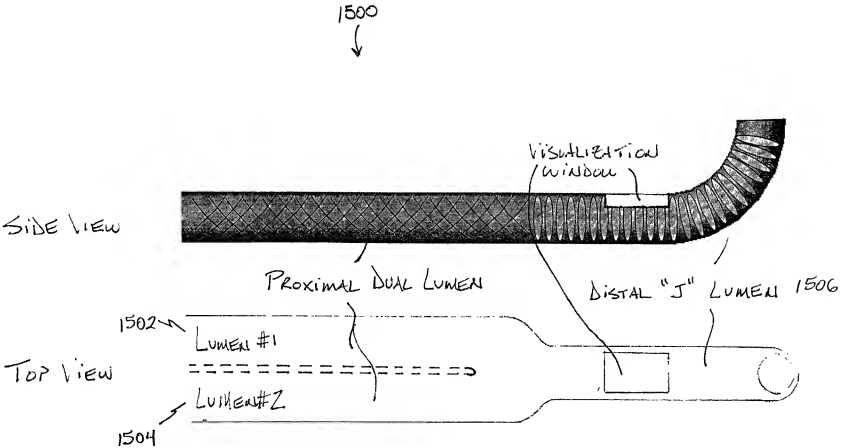

FIGURE 15

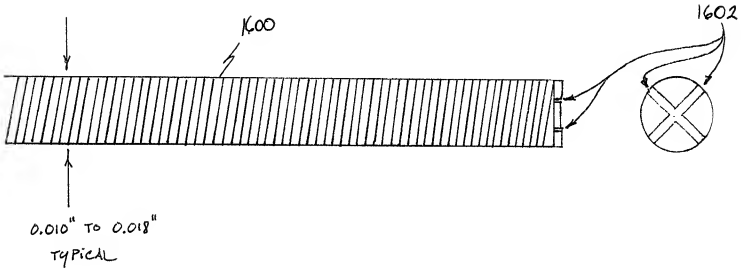

FIGURE 16

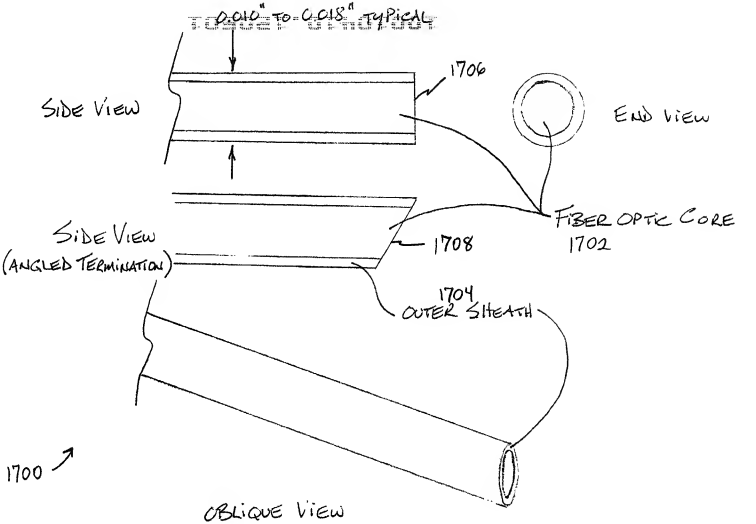
0.010" TO 0.018" TYPICAL
SIDE VIEW
1706
END VIEW
FIBER OPTIC CORE
1702
SIDE VIEW
(ANGLED TERMINATION)
1708
1704
OUTER SHEATH
1700
OBLIQUE VIEW

FIGURE 17A

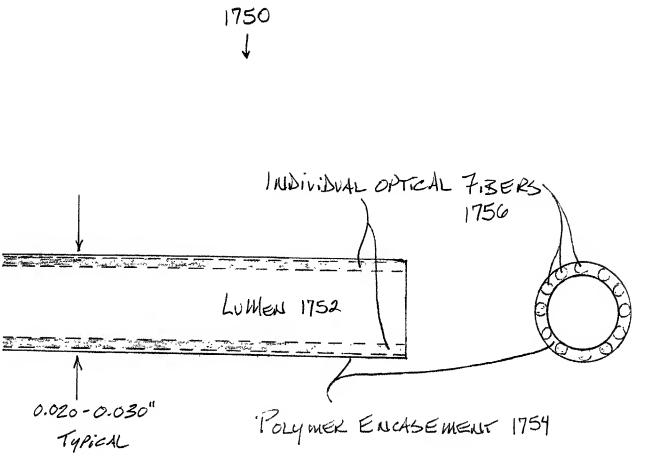

FIGURE 17B

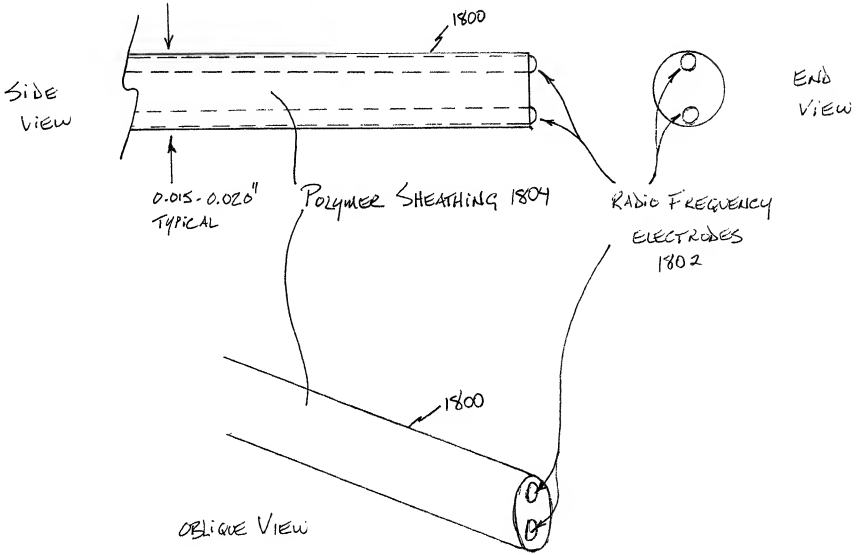

Figure 18

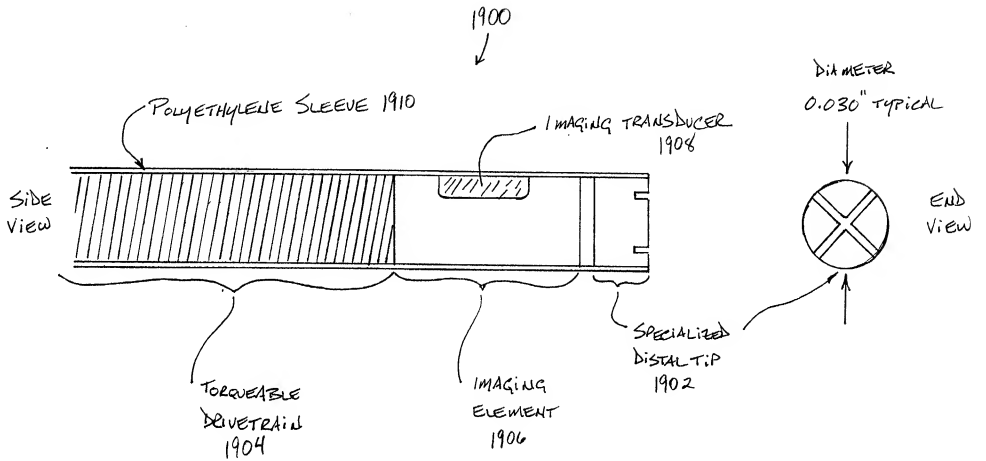

FIGURE 19

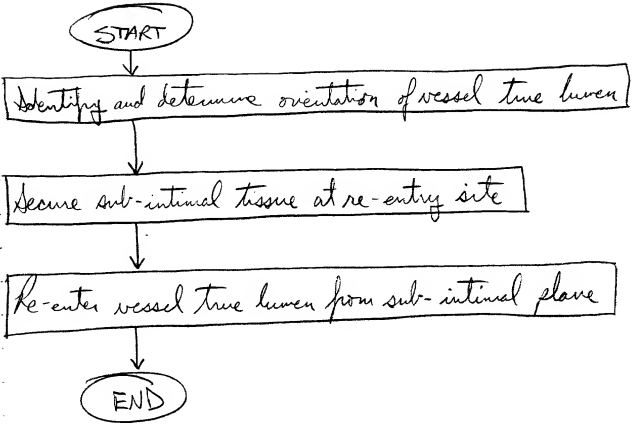
START
Identify and determine orientation of vessel true lumen
Secure sub-intimal tissue at re-entry site
Re-enter vessel true lumen from sub-intimal plane
END

FIGURE 20

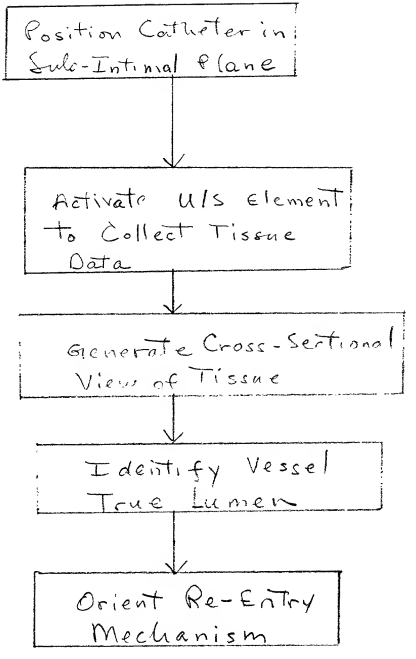
Position Catheter in Sub-Intimal Plane
Activate U/S Element to Collect Tissue Data
Generate Cross-Sectional View of Tissue
Identify Vessel True Lumen
Orient Re-Entry Mechanism

Figure 21

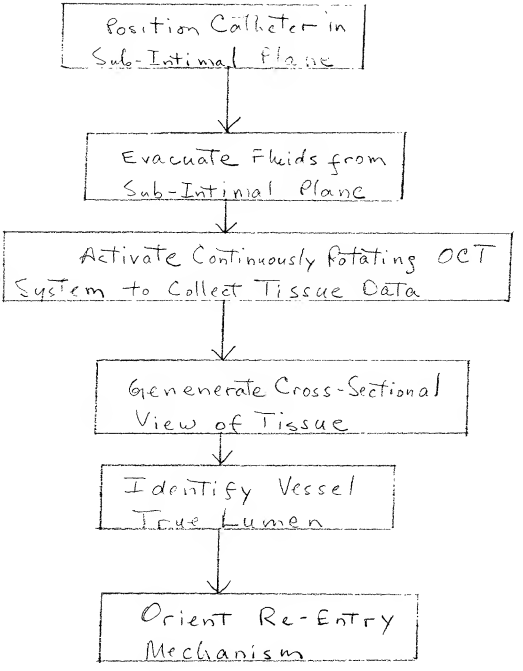
Position Catheter in Sub-Intimal Plane
Evacuate Fluids from Sub-Intimal Plane
Activate Continuously Rotating OCT System to Collect Tissue Data
Genenerate Cross-Sectional View of Tissue
Identify Vessel True Lumen
Orient Re-Entry Mechanism

Figure 22

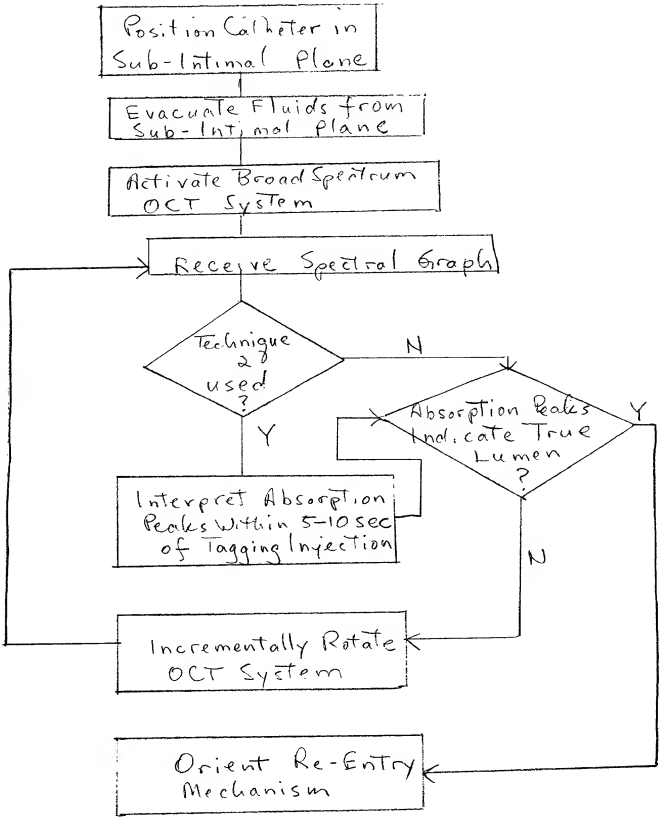
Position Catheter in Sub-Intimal Plane
Evacuate Fluids from Sub-Intimal Plane
Activate Broad Spectrum OCT System
Receive Spectral Graph
Technique 2 used ?
N
Y
Absorption Peaks Indicate True Lumen ?
Y
N
Interpret Absorption Peaks within 5-10 sec of Tagging Injection
Incrementally Rotate OCT System
Orient Re-Entry Mechanism

FIGURE 23

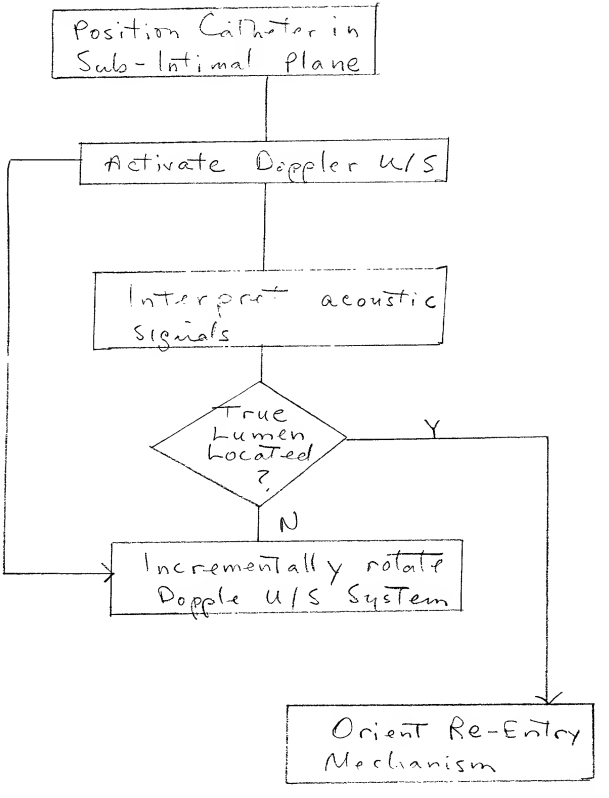
Position Catheter in Sub-Intimal Plane
Activate Doppler U/S
Interpret acoustic signals
True Lumen located ?
Y
N
Incrementally rotate Dopple U/S System
Orient Re-Entry Mechanism

Figure 24

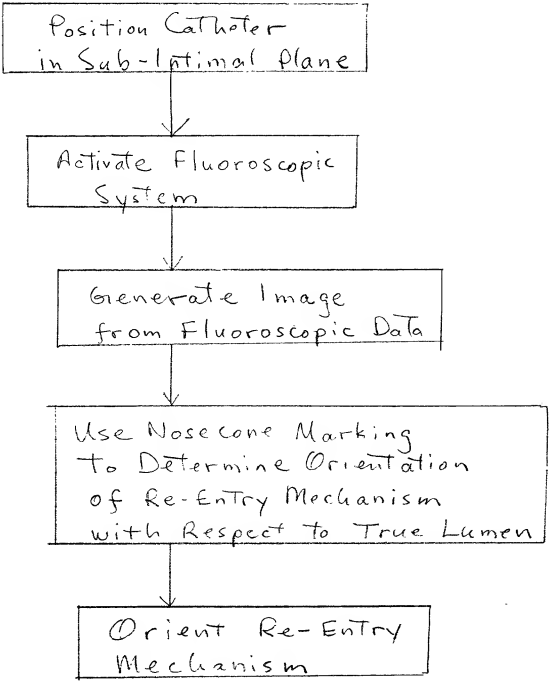
Position Catheter in Sub-Intimal Plane
Activate Fluoroscopic System
Generate Image from Fluoroscopic Data
Use Nosecone Marking to Determine Orientation of Re-Entry Mechanism with Respect to True Lumen
Orient Re-Entry Mechanism

Figure 25

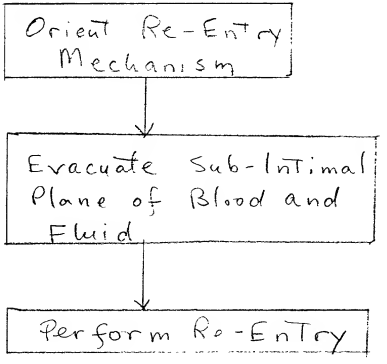
Orient Re-Entry Mechanism
Evacuate Sub-Intimal Plane of Blood and Fluid
Perform Re-Entry

Figure 26

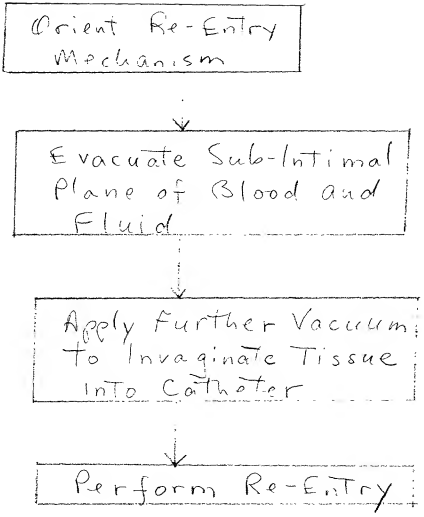
Orient Re-Entry Mechanism
Evacuate Sub-Intimal Plane of Blood and Fluid
Apply Further Vacuum to Invaginate Tissue into Catheter
Perform Re-Entry

Figure 27

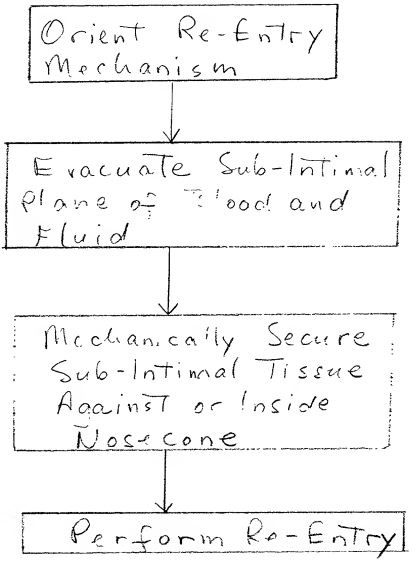
Orient Re-Entry Mechanism
Evacuate Sub-Intimal plane of Blood and Fluid
Mechanically Secure Sub-Intimal Tissue Against or Inside Nosecone
Perform Re-Entry

Figure 28

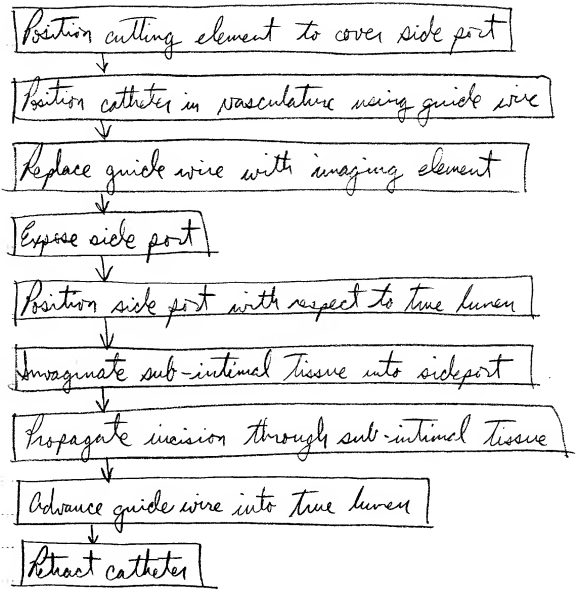
Position cutting element to cover side port
Position catheter in vasculature using guide wire
Replace guide wire with imaging element
Expose side port
Position side port with respect to true lumen
Invaginate sub-intimal tissue into sideport
Propagate incision through sub-intimal tissue
Advance guide wire into true lumen
Retract catheter

FIGURE 29

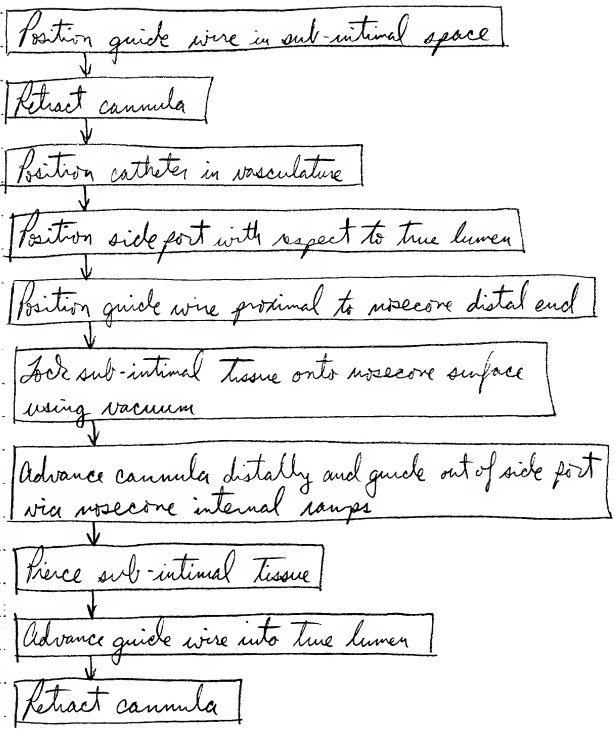
Position guide wire in sub-intimal space
Retract cannula
Position catheter in vasculature
Position side port with respect to true lumen
Position guide wire proximal to nosecone distal end
Lock sub-intimal tissue onto nosecone surface using vacuum
Advance cannula distally and guide out of side port via nosecone internal ramps
Pierce sub-intimal tissue
Advance guide wire into true lumen
Retract cannula

FIGURE 30

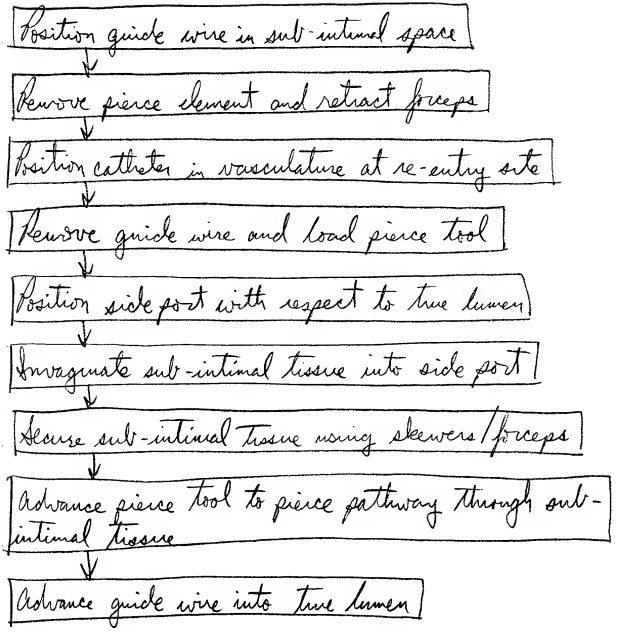
Position guide wire in sub-intimal space
Remove pierce element and retract forceps
Position catheter in vasculature at re-entry site
Remove guide wire and load pierce tool
Position side port with respect to true lumen
Invaginate sub-intimal tissue into side port
Secure sub-intimal tissue using skewers/forceps
Advance pierce tool to pierce pathway through sub-intimal tissue
Advance guide wire into true lumen

FIGURE 31

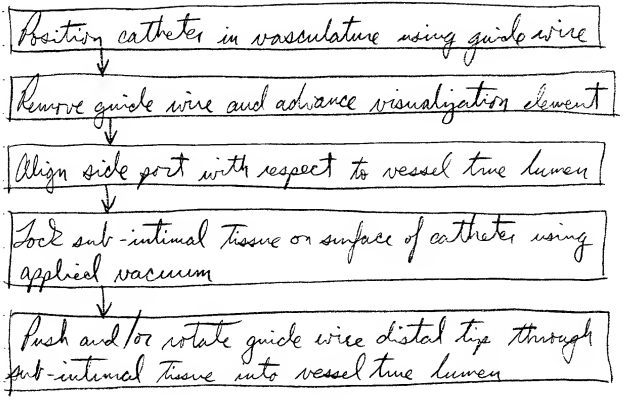
Position catheter in vasculature using guide wire
Remove guide wire and advance visualization element
Align side port with respect to vessel true lumen
Lock sub-intimal tissue or surface of catheter using applied vacuum
Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen

FIGURE 32

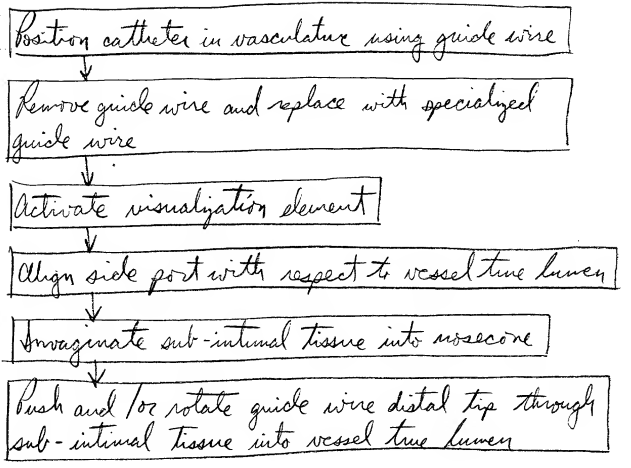
Position catheter in vasculature using guide wire
Remove guide wire and replace with specialized guide wire
Activate visualization element
Align side port with respect to vessel true lumen
Invaginate sub-intimal tissue into nosecone
Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen

FIGURE 33

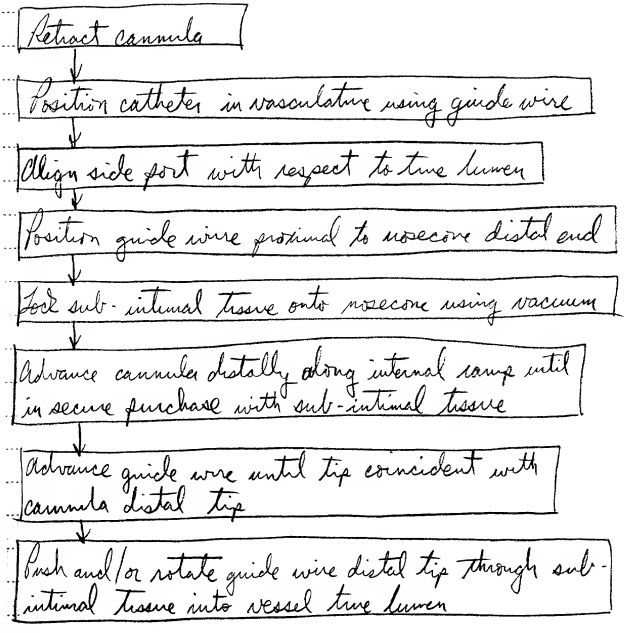
Retract cannula
Position catheter in vasculature using guide wire
Align side port with respect to true lumen
Position guide wire proximal to nosecone distal end
Lock sub-intimal tissue onto nosecone using vacuum
Advance cannula distally along internal ramp until in secure purchase with sub-intimal tissue
Advance guide wire until tip coincident with cannula distal tip
Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen

FIGURE 34

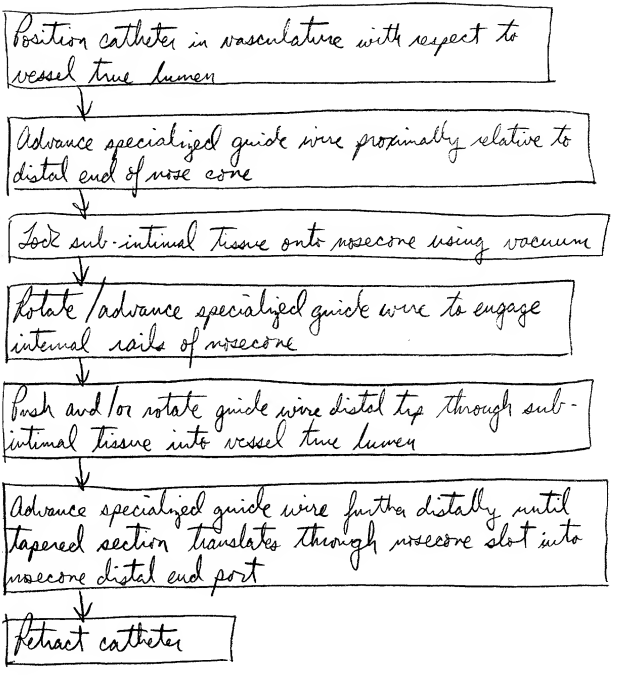
Position catheter in vasculature with respect to vessel true lumen
Advance specialized guide wire proximally relative to distal end of nose cone
Lock sub-intimal tissue onto nosecone using vacuum
Rotate/advance specialized guide wire to engage internal rails of nosecone
Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen
Advance specialized guide wire further distally until tapered section translates through nosecone slot into nosecone distal end port
Retract catheter

FIGURE 35

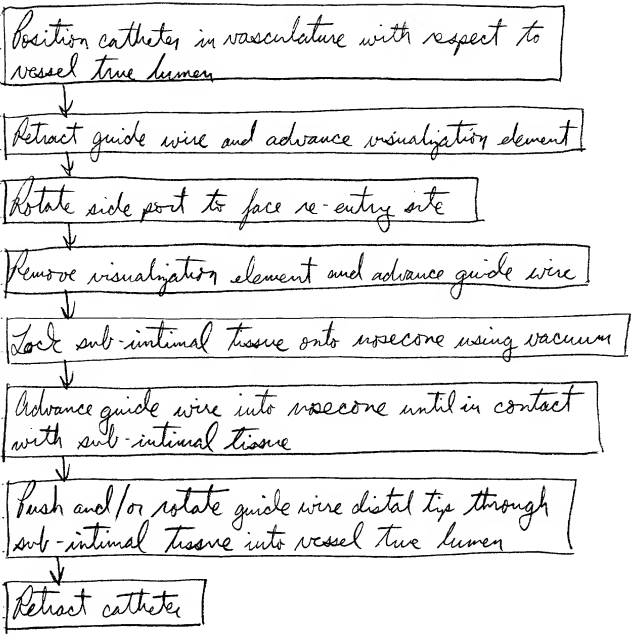
Position catheter in vasculature with respect to vessel true lumen
Retract guide wire and advance visualization element
Rotate side port to face re-entry site
Remove visualization element and advance guide wire
Lock sub-intimal tissue onto morecone using vacuum
Advance guide wire into morecone until in contact with sub-intimal tissue
Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen
Retract catheter

FIGURE 36

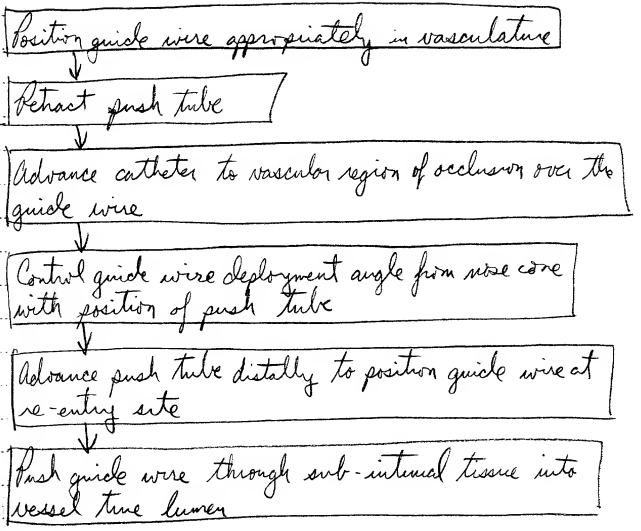
Position guide wire appropriately in vasculature
Retract push tube
Advance catheter to vascular region of occlusion over the guide wire
Control guide wire deployment angle from wire core with position of push tube
Advance push tube distally to position guide wire at re-entry site
Push guide wire through sub-intimal tissue into vessel true lumen

FIGURE 37

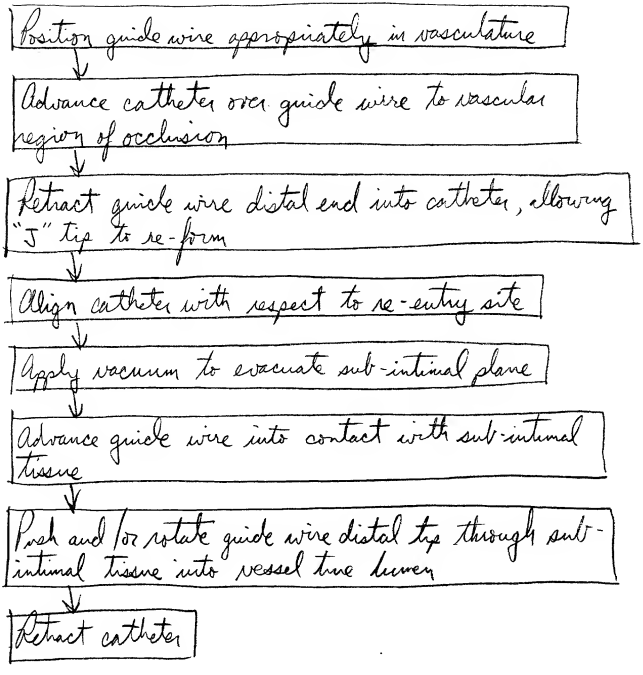
Position guide wire appropriately in vasculature
Advance catheter over guide wire to vascular region of occlusion
Retract guide wire distal end into catheter, allowing "J" tip to re-form
Align catheter with respect to re-entry site
Apply vacuum to evacuate sub-intimal plane
Advance guide wire into contact with sub-intimal tissue
Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen
Retract catheter

FIGURE 38

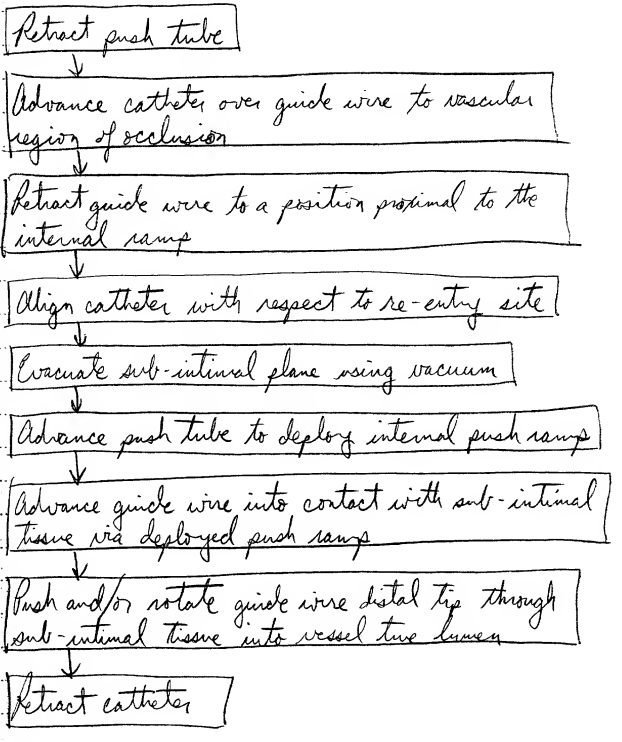
Retract push tube
Advance catheter over guide wire to vascular region of occlusion
Retract guide wire to a position proximal to the internal ramp
Align catheter with respect to re-entry site
Evacuate sub-intimal plane using vacuum
Advance push tube to deploy internal push ramp
Advance guide wire into contact with sub-intimal tissue via deployed push ramp
Push and/or rotate guide wire distal tip through sub-intimal tissue into vessel true lumen
Retract catheter

FIGURE 39

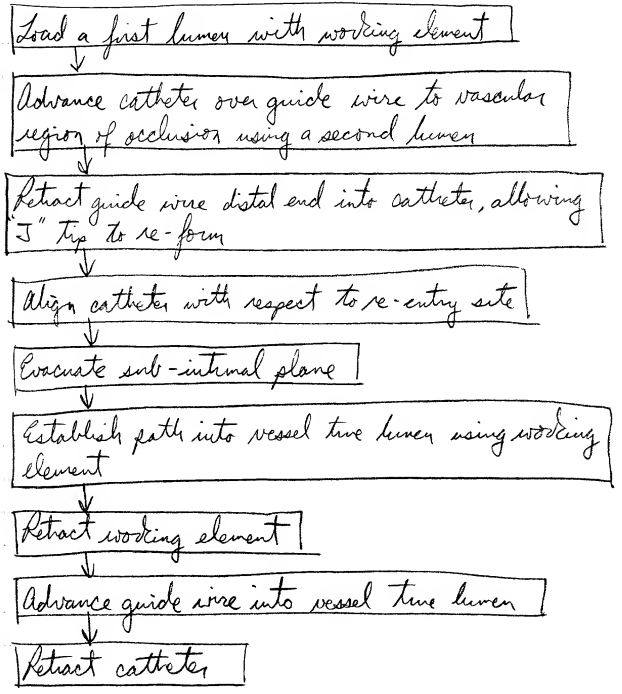
Load a first lumen with working element
Advance catheter over guide wire to vascular region of occlusion using a second lumen
Retract guide wire distal end into catheter, allowing "J" tip to re-form
Align catheter with respect to re-entry site
Evacuate sub-intimal plane
Establish path into vessel true lumen using working element
Retract working element
Advance guide wire into vessel true lumen
Retract catheter

FIGURE 40

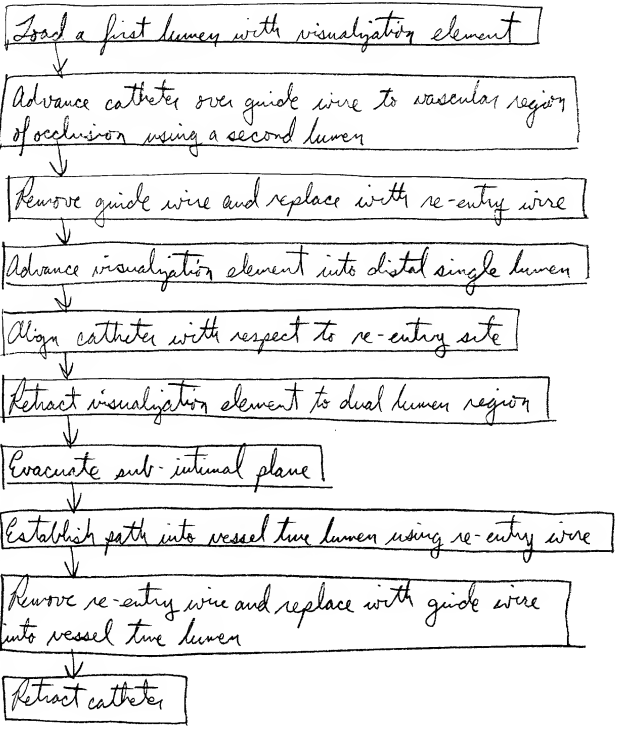
Load a first lumen with visualization element
Advance catheter over guide wire to vascular region of occlusion using a second lumen
Remove guide wire and replace with re-entry wire
Advance visualization element into distal single lumen
Align catheter with respect to re-entry site
Retract visualization element to dual lumen region
Evacuate sub-intimal plane
Establish path into vessel true lumen using re-entry wire
Remove re-entry wire and replace with guide wire into vessel true lumen
Retract catheter

FIGURE 41

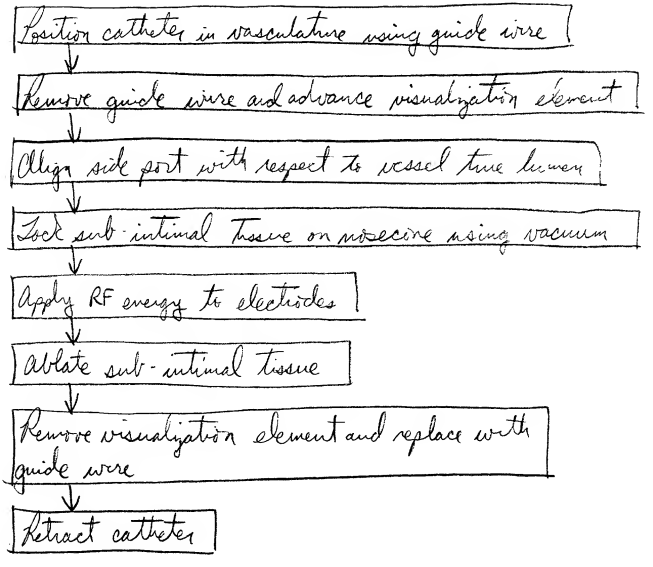
Position catheter in vasculature using guide wire
Remove guide wire and advance visualization element
Align side port with respect to vessel true lumen
Lock sub-intimal tissue on projection using vacuum
Apply RF energy to electrodes
Ablate sub-intimal tissue
Remove visualization element and replace with guide wire
Retract catheter

FIGURE 42

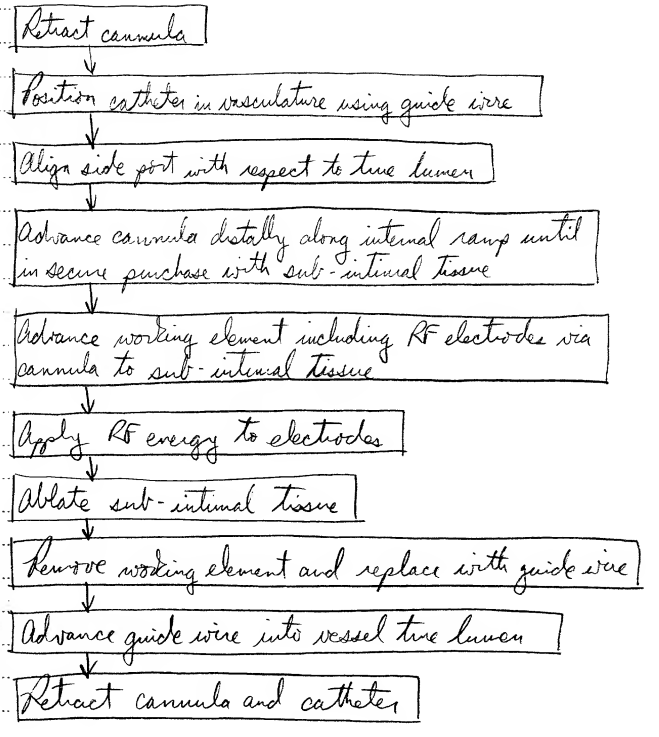
Retract cannula
Position catheter in vasculature using guide wire
Align side port with respect to true lumen
Advance cannula distally along internal ramp until in secure purchase with sub-intimal tissue
Advance working element including RF electrodes via cannula to sub-intimal tissue
Apply RF energy to electrodes
Ablate sub-intimal tissue
Remove working element and replace with guide wire
Advance guide wire into vessel true lumen
Retract cannula and catheter

FIGURE 43

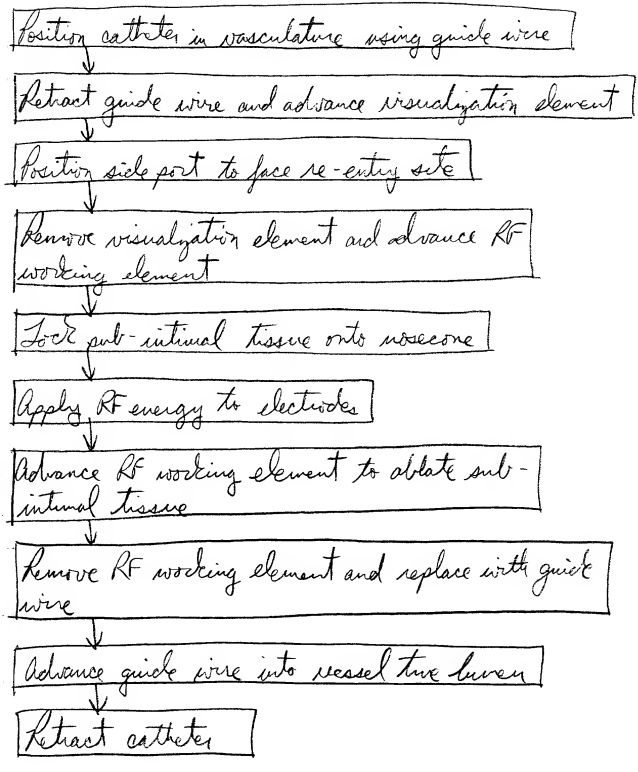
Position catheter in vasculature using guide wire
Retract guide wire and advance visualization element
Position side port to face re-entry site
Remove visualization element and advance RF working element
Lock sub-intimal tissue onto nosecone
Apply RF energy to electrodes
Advance RF working element to ablate sub-intimal tissue
Remove RF working element and replace with guide wire
Advance guide wire into vessel true lumen
Retract catheter

FIGURE 44

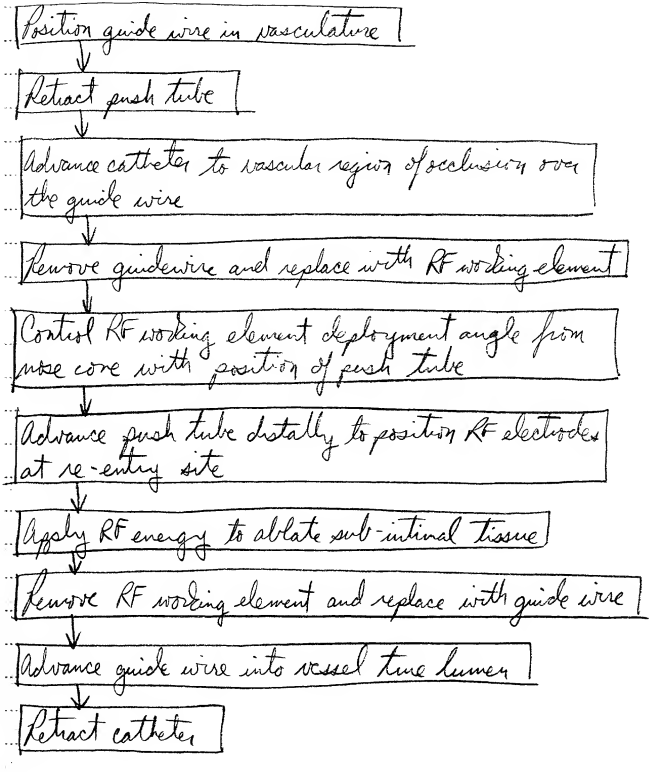
Position guide wire in vasculature
Retract push tube
Advance catheter to vascular region of occlusion over the guide wire
Remove guidewire and replace with RF working element
Control RF working element deployment angle from proximal core with position of push tube
Advance push tube distally to position RF electrodes at re-entry site
Apply RF energy to ablate sub-intimal tissue
Remove RF working element and replace with guide wire
Advance guide wire into vessel true lumen
Retract catheter

FIGURE 45

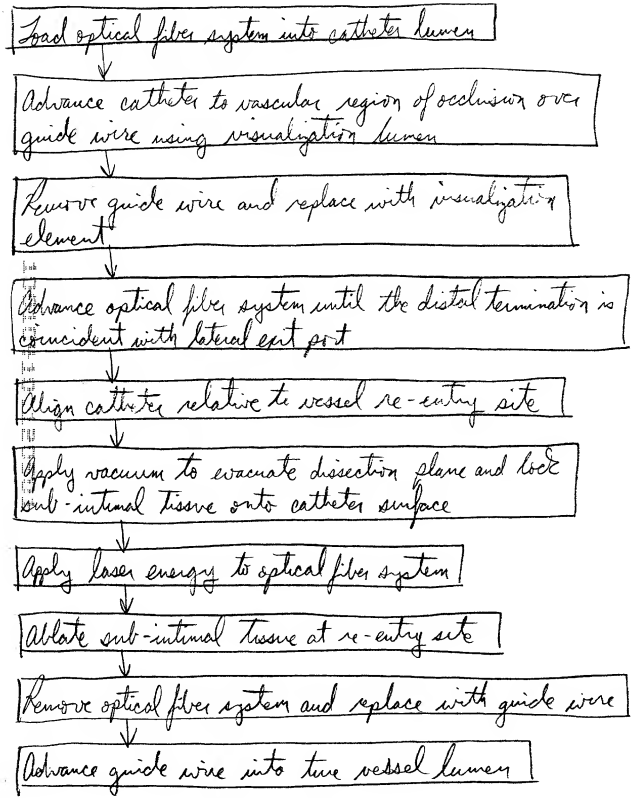
Load optical fiber system into catheter lumen
Advance catheter to vascular region of occlusion over guide wire using visualization lumen
Remove guide wire and replace with visualization element
Advance optical fiber system until the distal termination is coincident with lateral exit port
Align catheter relative to vessel re-entry site
Apply vacuum to evacuate dissection plane and lock sub-intimal tissue onto catheter surface
Apply laser energy to optical fiber system
Ablate sub-intimal tissue at re-entry site
Remove optical fiber system and replace with guide wire
Advance guide wire into true vessel lumen

FIGURE 46

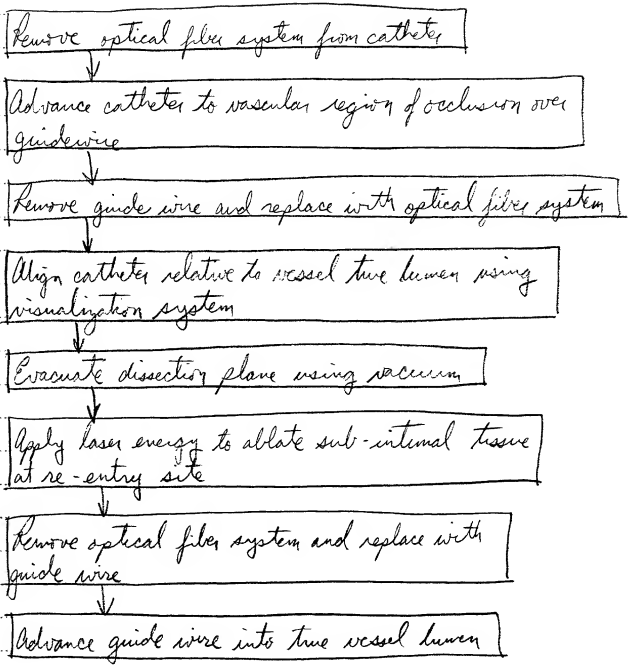
Remove optical fiber system from catheter
Advance catheter to vascular region of occlusion over guidewire
Remove guide wire and replace with optical fiber system
Align catheter relative to vessel true lumen using visualization system
Evacuate dissection plane using vacuum
Apply laser energy to ablate sub-intimal tissue at re-entry site
Remove optical fiber system and replace with guide wire
Advance guide wire into true vessel lumen

FIGURE 47

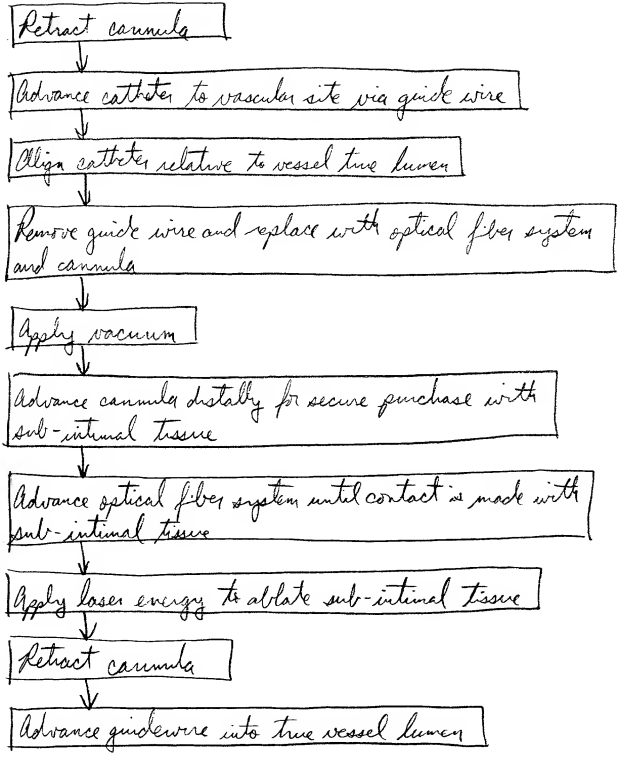
Retract cannula
Advance catheter to vascular site via guide wire
Align catheter relative to vessel true lumen
Remove guide wire and replace with optical fiber system and cannula
Apply vacuum
Advance cannula distally for secure purchase with sub-intimal tissue
Advance optical fiber system until contact is made with sub-intimal tissue
Apply laser energy to ablate sub-intimal tissue
Retract cannula
Advance guidewire into true vessel lumen

FIGURE 48

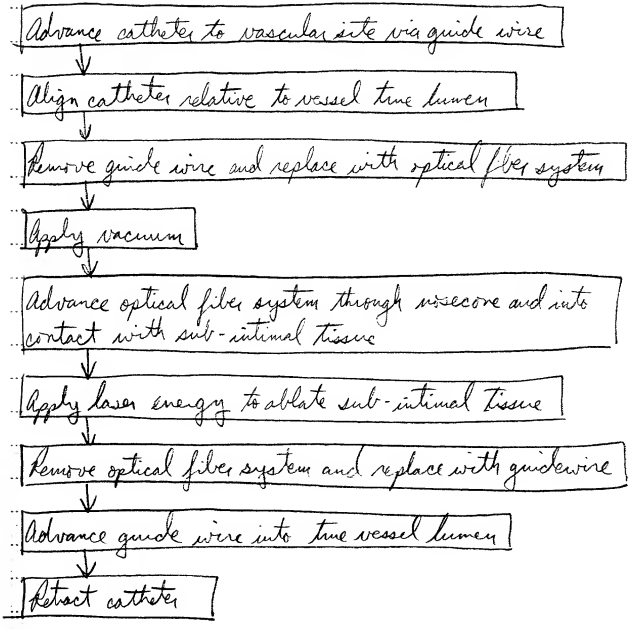
Advance catheter to vascular site via guide wire
Align catheter relative to vessel true lumen
Remove guide wire and replace with optical fiber system
Apply vacuum
Advance optical fiber system through nosecone and into contact with sub-intimal tissue
Apply laser energy to ablate sub-intimal tissue
Remove optical fiber system and replace with guidewire
Advance guide wire into true vessel lumen
Retract catheter

FIGURE 49

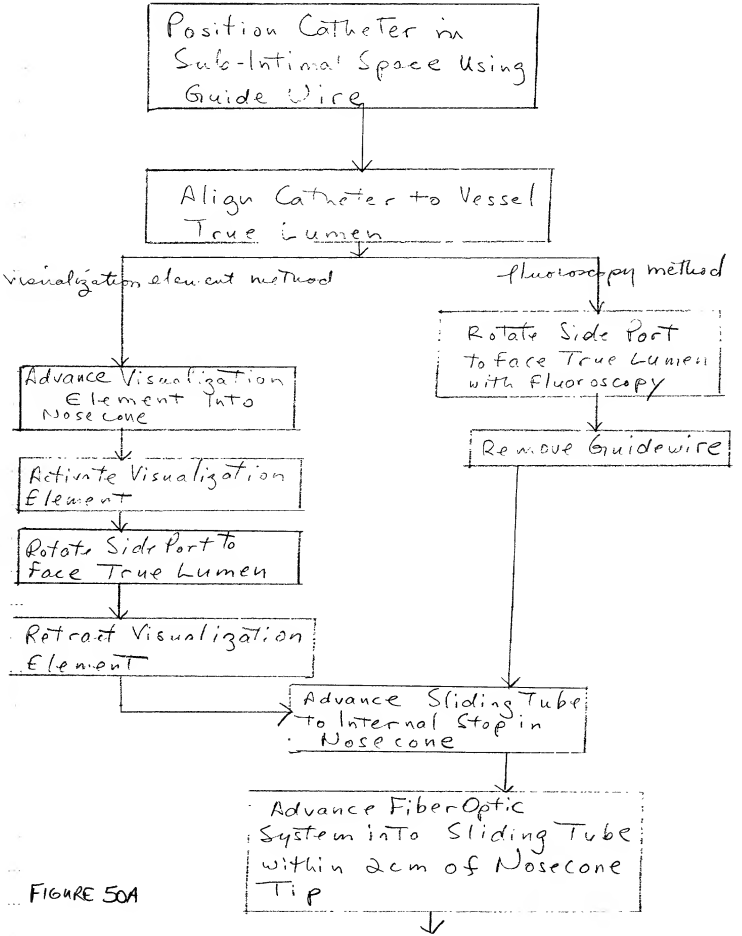
Position Catheter in Sub-Intimal Space Using Guide Wire
Align Catheter to Vessel True Lumen
visualization element method
fluoroscopy method
Rotate Side Port to face True Lumen with Fluoroscopy
Advance Visualization Element into Nosecone
Remove Guidewire
Activate Visualization Element
Rotate Side Port to Face True Lumen
Retract Visualization Element
Advance Sliding Tube to Internal Stop in Nosecone
Advance Fiber Optic System into Sliding Tube within 2cm of Nosecone Tip

FIGURE 50A

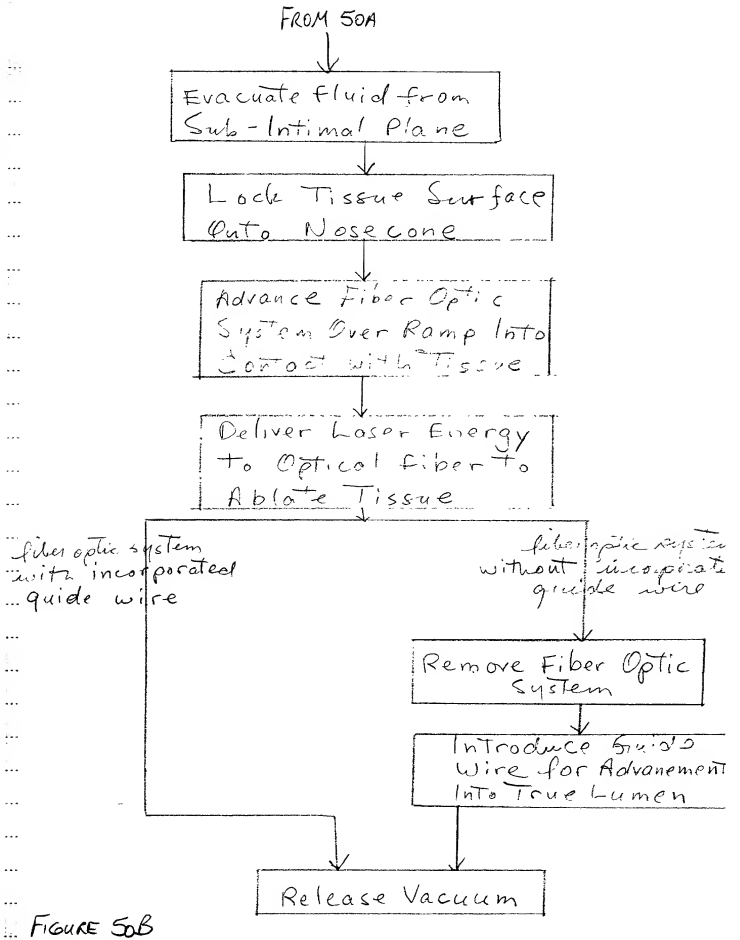
FROM 50A
Evacuate Fluid from Sub-Intimal Plane
Lock Tissue Surface Onto Nosecone
Advance Fiber Optic System Over Ramp Into Contact with Tissue
Deliver Laser Energy to Optical fiber to Ablate Tissue
fiber optic system with incorporated quide wire
fiber optic system without incorporate guide wire
Remove Fiber Optic System
Introduce Guide Wire for Advanement Into True Lumen
Release Vacuum

FIGURE 50B

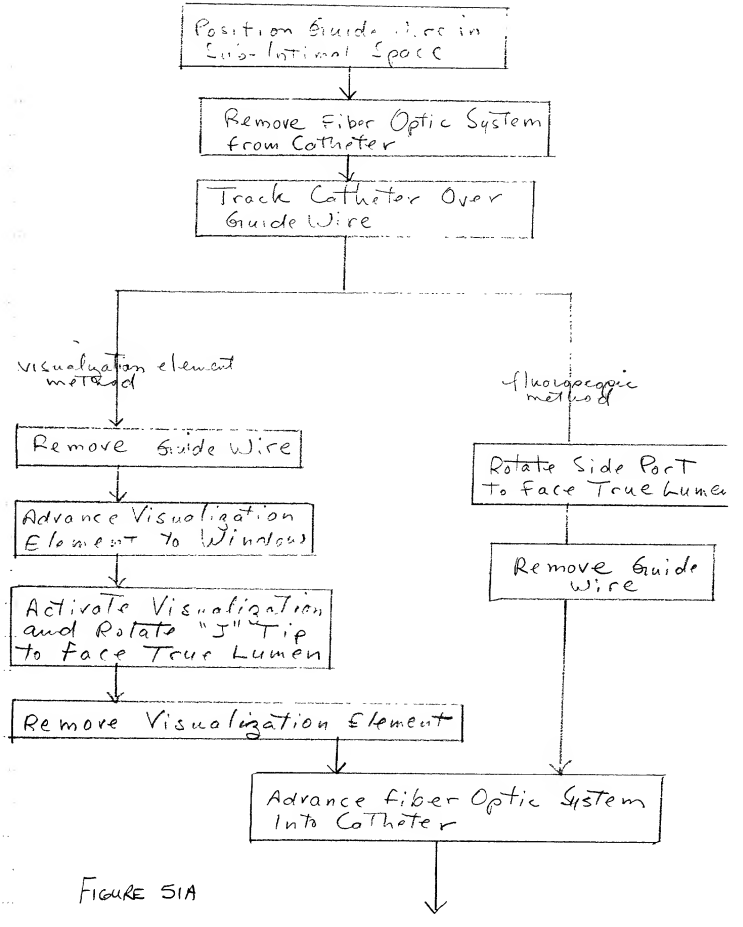
Position Guide Wire in Sub-Intimal Space
Remove Fiber Optic System from Catheter
Track Catheter Over Guide Wire
visualization element method
fluoroscopic method
Remove Guide Wire
Advance Visualization Element to Window
Activate Visualization and Rotate "J" Tip to Face True Lumen
Remove Visualization Element
Rotate Side Port To Face True Lumen
Remove Guide Wire
Advance Fiber Optic System Into Catheter

FIGURE 51A

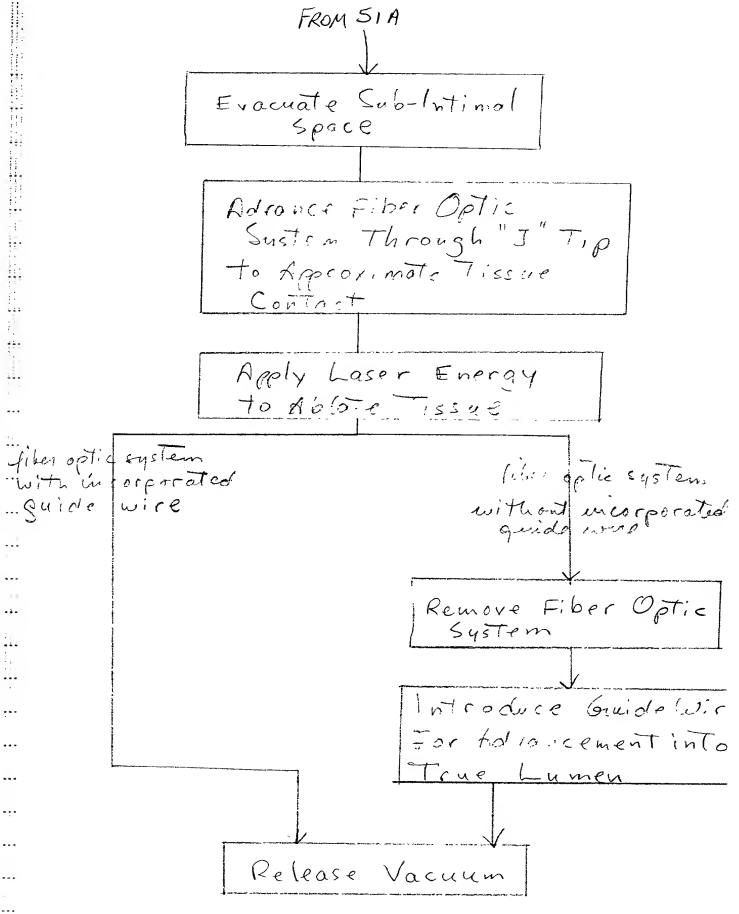
FROM 51A
Evacuate Sub-Intimal Space
Advance Fiber Optic System Through "J" Tip to Approximate Tissue Contact
Apply Laser Energy to Ablate Tissue
fiber optic system with incorporated guide wire
fiber optic system without incorporated guide wire
Remove Fiber Optic System
Introduce Guidewire for Advancement into True Lumen
Release Vacuum

FIGURE 51B

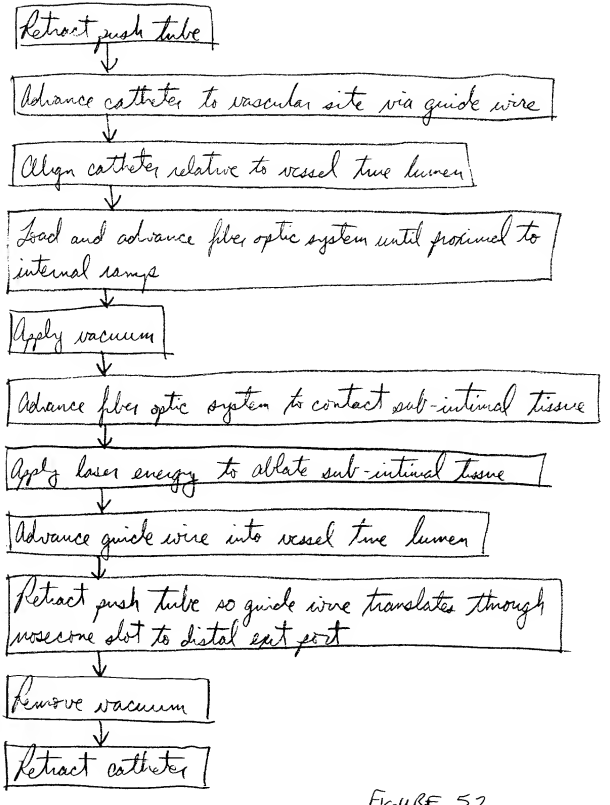
Retract push tube
Advance catheter to vascular site via guide wire
Align catheter relative to vessel true lumen
Load and advance fiber optic system until proximal to internal ramps
Apply vacuum
Advance fiber optic system to contact sub-intimal tissue
Apply laser energy to ablate sub-intimal tissue
Advance guide wire into vessel true lumen
Retract push tube so guide wire translates through monocore slot to distal exit port
Remove vacuum
Retract catheter

FIGURE 52